

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014

IN THE CLAIMS:

1-4. (Cancelled)

5. (Previously Presented) A composition comprising:

a cyclodextrin-containing polymer,

a therapeutic agent, and

a complexing agent, comprising:

at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and

at least one polymer portion that increases solubility and/or imparts stabilization relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone;

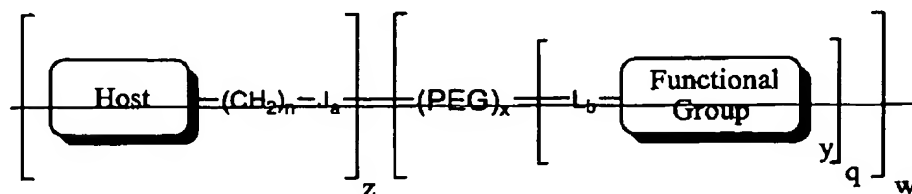
wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.

6. (Previously Presented) A composition of claim 5, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.

7. (Original) A composition of claim 6, wherein said therapeutic agent is a polynucleotide.

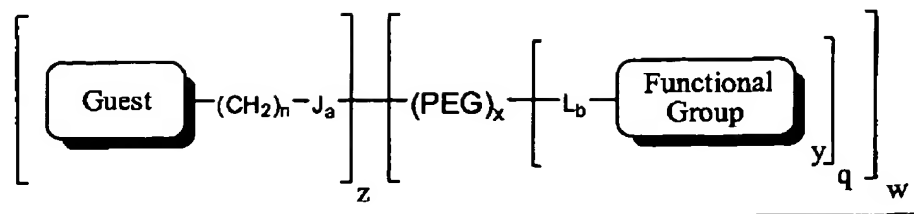
8-11. (Cancelled)

12. (Currently Amended) A composition of claim 5, wherein the complexing agent is a compound of the formula:



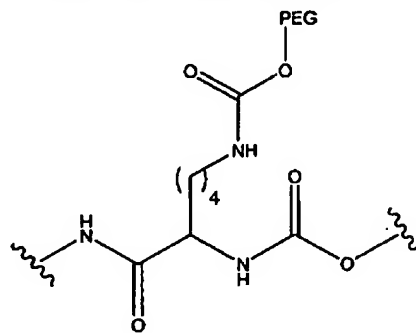
U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014



wherein

J is $-\text{NH}-$, $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$, $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$, $-\text{CH}_2\text{SS}-$, $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



$(\text{CH}_2)_e-\text{Y})\text{O}-$,

, a peptide or polypeptide residue, or

$-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$;

Y is an additional host-guest functionality;

R^1 is $-(\text{CH}_2)-\text{CO}_2\text{H}$, an ester or salt thereof, or $-(\text{CH}_2)_a-\text{CONH}_2$;

PEG is $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$, where z varies from 2 to 500;

L is H, $-\text{NH}-$, $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-(\text{C}=\text{O})-\text{CH}_2-$, $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$, $-\text{SS}-$, $-\text{C}(=\text{O})\text{O}-$, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

q ranges from 1 to 5;

w ranges from 1 to 5;

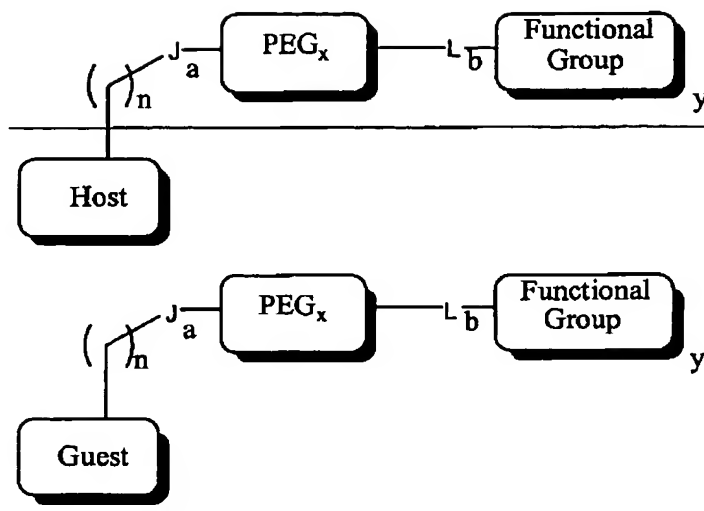
y is 1; and

x is 0 or 1.

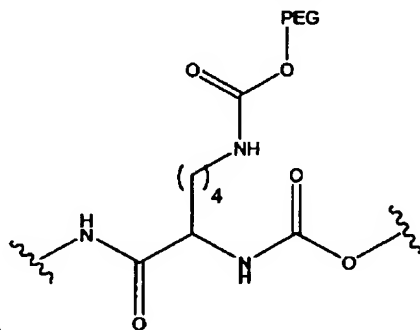
13. (Currently Amended) A composition of claim 5, wherein the complexing agent is a compound of the formula:

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014



wherein

J is $-\text{NH}-$, $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$, $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$, $-\text{CH}_2\text{SS}-$, $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$ 

$(\text{CH}_2)_e-\text{Y})\text{O}-$, , a peptide or polypeptide residue, or
 $-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$;

Y is an additional host-guest functionality;

 R^1 is $-(\text{CH}_2)_3-\text{CO}_2\text{H}$, an ester or salt thereof; or $-(\text{CH}_2)_3-\text{CONH}_2$;PEG is $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$, where z varies from 2 to 500;L is H, $-\text{NH}-$, $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-(\text{C}=\text{O})-\text{CH}_2-$, $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$, $-\text{SS}-$, $-\text{C}(=\text{O})\text{O}-$, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014

y is 1; and

x is 0 or 1.

14. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

15. (Previously Presented) A composition of claim 5, wherein the polymer portion increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

16. (Previously Presented) A composition of claim 5, wherein the polymer portion stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

17. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a therapeutic agent reversibly bound to the complexing agent.

18. (Previously Presented) A composition of claim 5, wherein the complexing agent further comprises a spacer group.

19-22. (Cancelled)

23. (Previously Presented) A composition of claim 5, wherein at least one polymer portion of the complexing agent comprises PEG or derivatives thereof.

24-26. (Cancelled)

27. (Previously Presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

U.S. Serial No.: 10/021,294

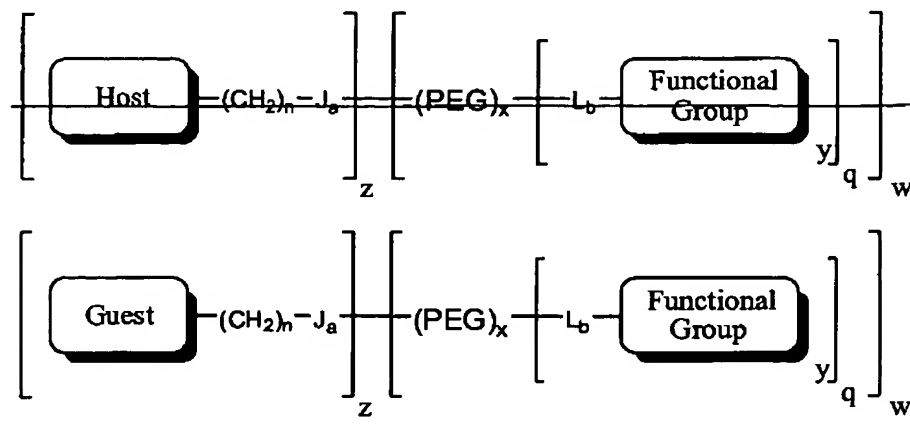
Attorney Docket No.: CTCH-P01-014

28. (Previously Presented) A composition of claim 5, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.
29. (Cancelled)
30. (Previously Presented) A composition comprising:
a cyclodextrin-containing polymer,
a therapeutic agent, and
a complexing agent, comprising:
 at least one functional group,
 at least one guest moiety that forms an inclusion complex with a host moiety of said cyclodextrin-containing polymer, wherein the guest moiety is selected from adamantyl, naphthyl, cholesterol, and combinations thereof, and
 at least one polymeric spacer group;
wherein the cyclodextrin-containing polymer, the therapeutic agent, and the complexing agent are separate molecules.
31. (Previously Presented) A composition of claim 30, wherein said therapeutic agent is selected from an antibiotic, a steroid, a polynucleotide, small molecule pharmaceutical, a virus, a plasmid, a peptide, a peptide fragment, a chelating agent, a biologically active macromolecule, and mixtures thereof.
32. (Previously Presented) A composition of claim 31, wherein said therapeutic agent is a polynucleotide.
33. (Cancelled)
34. (Previously Presented) A composition of claim 30, wherein at least one spacer group of the complexing agent comprises PEG or derivatives thereof.

U.S. Serial No.: 10/021,294

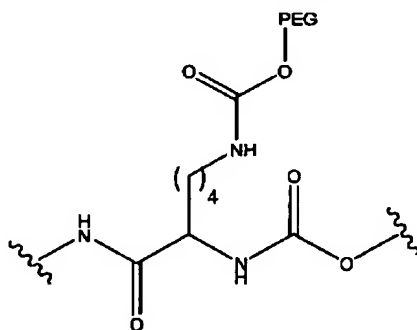
Attorney Docket No.: CTCH-P01-014

35. (Currently Amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is $-\text{NH}-$, $-\text{C}(=\text{O})\text{NH}-\text{CH}_2-$, $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$, $-\text{CH}_2\text{SS}-$, $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



$(\text{CH}_2)_e-\text{Y})\text{O}-$,

, a peptide or polypeptide residue, or

$-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-(\text{C}=\text{O})-\text{CH}(\text{R}^1)-\text{NH}-$;

Y is an additional host-guest functionality;

R^1 is $-(\text{CH}_2)_a-\text{CO}_2\text{H}$, an ester or salt thereof; or $-(\text{CH}_2)_a-\text{CONH}_2$;

PEG is $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$, where z varies from 2 to 500;

L is H, $-\text{NH}$, $-\text{NH}-(\text{C}=\text{O})-(\text{CH}_2)_e-\text{C}(=\text{O})-\text{CH}_2-$, $-\text{S}(=\text{O})_2-\text{HC}=\text{CH}-$, $-\text{SS}-$, $-\text{C}(=\text{O})\text{O}-$, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014

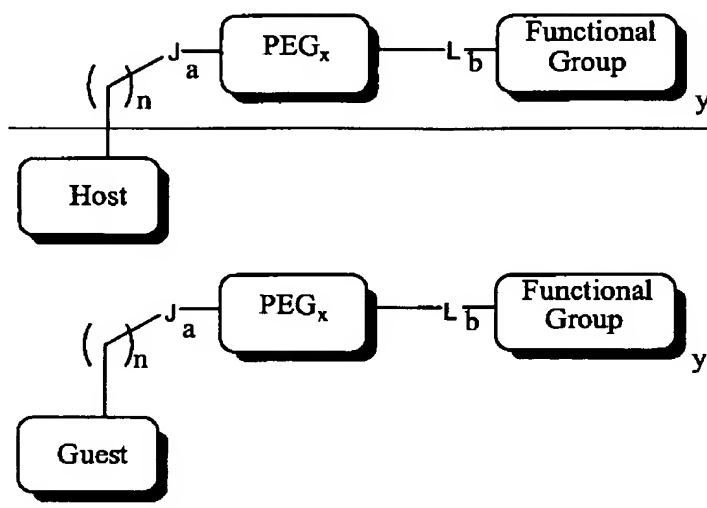
q ranges from 1 to 5;

w ranges from 1 to 5;

y is 1; and

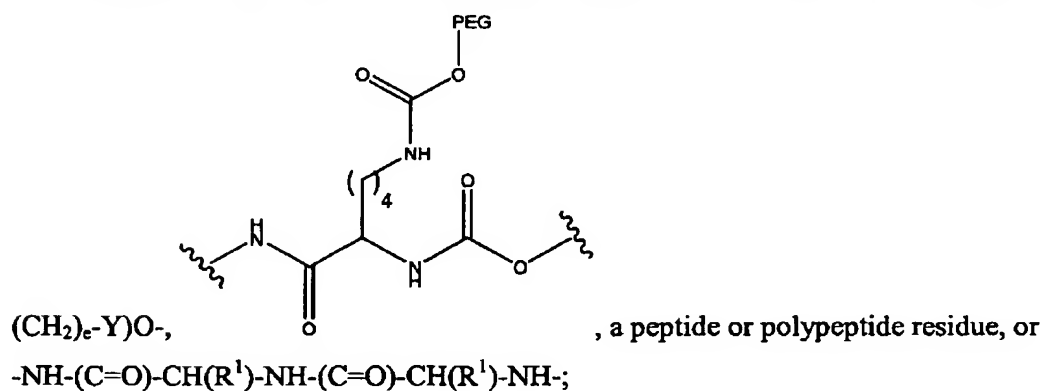
x is 1.

36. (Currently Amended) A composition of claim 34, wherein the complexing agent is a compound of the formula:



wherein

J is $-\text{NH}-$, $-\text{C}(=\text{O})\text{NH}-\text{CH}_2$, $-\text{NH}-\text{C}(=\text{O})-(\text{CH}_2)_d-$, $-\text{CH}_2\text{SS}-$, $-\text{C}(=\text{O})\text{O}-(\text{CH}_2)_e-\text{O}-\text{P}(=\text{O})(\text{O}-$



Y is an additional host-guest functionality;

R^1 is $-(\text{CH}_2)-\text{CO}_2\text{H}$, an ester or salt thereof; or $-(\text{CH}_2)_x-\text{CONH}_2$;

PEG is $-\text{O}(\text{CH}_2\text{CH}_2\text{O})_z-$, where z varies from 2 to 500;

U.S. Serial No.: 10/021,294

Attorney Docket No.: CTCH-P01-014

L is H, -NH, -NH-(C=O)-(CH₂)_c-(C=O)-CH₂-, -S(=O)₂-HC=CH-, -SS-, -C(=O)O-, or a carbohydrate residue;

a is 0 or 1;

b is 0 or 1;

d ranges from 0 to 6;

e ranges from 1 to 6;

n ranges from 0 to 6;

y is 1; and

x is 1.

37. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a group selected from a ligand, a nuclear localization signal, an endosomal release peptide, an endosomal release polymer, or a membrane permeabilization agent.

38. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a moiety that increases the solubility of the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

39. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a moiety that stabilizes the composition under biological conditions relative to a composition of the cyclodextrin-containing polymer and therapeutic agent alone.

40. (Previously Presented) A composition of claim 30, wherein at least one functional group includes a therapeutic agent reversibly bound to the complexing agent.

41. (Previously Presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises one or more cyclodextrins in side chains of the cyclodextrin-containing polymer.

42. (Previously Presented) A composition of claim 30, wherein the cyclodextrin-containing polymer comprises a linear cyclodextrin-containing polymer wherein cyclodextrin moieties are present in the backbone of the polymer.